

**R E M A R K S**

Claims 5-8 and 13-17 are pending in the present application. The Applicants have amended Claims 5 and 13 to correct a typographical error. Marked up versions of the claims, showing all the changes relative to the previous version of the paragraphs and claims, are provided on separate pages at the end of this Response, in accordance with 37 CFR 1.121(b)(1)(iii) and 1.121(c)(1)(ii). For the Examiner's convenience, the Applicant's have provided Courtesy Copy of a clean set of claims, amended as proposed, following this Response after the pages with the marked up versions of the amended paragraph and claims, and after any attachments.

The previous objection to the disclosure in the final Office Action (mailed January 9, 2001) on the grounds that the R groups as shown on page 7 are improperly defined has been implicitly withdrawn, as it was not repeated in this first Office Action after an RCE.

The following rejections are at issue, and are set forth by number in the order that they are herein addressed:

- 1) Claims 5-8 and 13-17 are rejected 35 U.S.C. §103(a) as allegedly obvious over Cain *et al.* (WO 97/18320).
- 2) Claims 5-8 and 13-17 are rejected under 35 U.S.C. §103(a) as allegedly obvious over Nilsen *et al.* (U.S. Pat. No. 5,885,594) in view of Cook *et al.* (U.S. Pat. No. 5,554,646), further in view of Chin *et al.* (IDS April 13, 2000, 39).
- 3) Claims 5-8 and 13-17 are rejected under 35 U.S.C. §103(a) as allegedly obvious over Timmermann *et al.* (WO 98/49129, No. 25 in the IDS of April 13, 2000) in view of Cook *et al.* (U.S. Pat. No. 5,554,646), further in view of Chin *et al.* (IDS April 13, 2000, 39).

The Applicants believe that the following remarks traverse the Examiner's rejection of the claims.

**Three Requirements Must be Met to Establish a *prima facie* Case of Obviousness**

It is well known that there are three requirements to establish a *prima facie* case of obviousness, and that all three must be met by the Examiner. Failure to establish any one of these three requirements precludes finding of a *prima facie* case of obviousness, and, without more, entitles the Applicants to allowance of the claims at issue (*See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990)). These three requirements are first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP § 2143).

The Applicants respectfully submit that the pending claims are not obvious, as the prior art cited by the Examiner does not meet even one of these three requirements.

**Claims 5-8 and 13-17 are Not Obvious**

1. Claims 5-8 and 13-17 are rejected 35 U.S.C. §103(a) as allegedly obvious over Cain *et al.* (WO 97/18320).

The Examiner asserts that Cain *et al.* teaches "an acylglycerol composition comprising mono-di-and tri-glyceride wherein the fatty acid are c9,t11 CLA or t10,c12 CLA, no other isomer was employed for the esterification forming the acylglycerol composition" (Office Action, page 2).

The Applicants respectfully point out first that in the Examples cited by the Examiner, after isomerization of sunflower oil, 38.1% or 36.2 % of the fatty acid product is not characterized (Examples 6 and 7), and that the total fatty acid product was used to prepare acylglycerol products. Therefore, the Examiner's statement that "Cain teaches an acylglycerol composition comprising mono- di- and tri-glyceride wherein the fatty acid are c9,t11 CLA or t10,c12 CLA, no other isomer was employed for the esterification" (Office Action, page 2) is incorrect.

Moreover, after the preparation of acylglycerol products, the amount of free fatty acid was described by Cain *et al.* as either 83.4% (Example 6) or 58 % (Example 7, calculated as

the amount remaining from a conversion of 42% of the fatty acid product to acylglycerols). However, the reference provides absolutely no quantitation of how much of the esterified fatty acid was CLA and how much was another fatty acid. Thus, the reference does NOT indicate whether the esterified fatty acid is "at least approximately 30% t10,c12 octadecadienoic acid and at least approximately 30% c9,t11 octadecadienoic acid" as is claimed. Note that the Examiner admits that the references does not expressly teach the amount of each of the isomers (Office Action, page 2), although the Examiner incorrectly implies that each of the isomers must be 30% or more of the total CLA moieties (Office Action, page 2), in contrast to the claim language quoted above.

However, the Examiner states that the "optimization of the ratio of the two [CLA] moieties....is considered within the skill of artisan, absent evidence to the contrary" (Office Action, page 2). The Applicants respectfully point out that they have previously supplied ample evidence to the contrary in their responses to the first two Office Actions. In the most recent response (filed April 4, 2001), the Applicants cite to their own specification, in which they describe their discovery of a problem with CLA products made by conventional approaches, which is the heterogeneity and the substantial variation in isoforms from batch to batch of the CLA (see, for example, specification page 4, lines 9-10). The Applicants solved the problem with a novel composition of isomerized fatty acids. But in order to obtain the novel compositions, it was necessary to develop a novel method of isomerization. The fatty acids of the novel composition are prepared by employing the novel method, which is a carefully controlled reaction, and which results in a high percentage of linoleic acid converted primarily to the conjugated c9,t11 and t10,c12 isomers so that less than a combined 1 percent of the 11,13 isomers, less than 1 percent of the 8,10 isomers, and less than 1 percent of the double trans species is present (see, for example, specification page 5, lines 5-14). This is in contrast to conventional compositions. In fact the Applicants specify that the 1 percent limit in concentration of the 11,13, 8,10, and trans-trans isomers serves as a convenient and practical **quality assurance standard of purity** (see, for example, specification page 5, lines 11-14, emphasis added).

As additional evidence, in the first Response (filed November 6, 2000), the Applicants directed the Examiner's attention to Sugano *et al.* (attached to this Response at Tab 1). This

reference may be compared to those cited by the Examiner. For example, comparison of Sugano *et al.* to Cain *et al.* reveals that Sugano *et al.* prepared CLA by a method similar to that utilized by Cain *et al.* In both methods, conjugation was performed in ethylene glycol at 180 °C. The main differences are that Cain *et al.* used sunflower oil as the fatty acid source, as opposed to the purified linoleic acid utilized by Sugano, Cain *et al.* utilized NaOH as the catalyst, as opposed to the KOH used by Sugano *et al.*, and Cain *et al.* heated the mixture for 3.0 hours, as opposed to the 2.0 hours used by Sugano *et al.*. Note that the Applicants have taught that the level of undesirable isomers increases with increased temperature and time of the isomerization reaction; note also the Sugano *et al.* utilized a purer starting material than did Cain *et al.* Even so, Sugano *et al.* disclose that their CLA contained 18.6% trans-trans isomers and 13.7% other isomers, in addition to the c9,t11 and t10,c12 isomers. Thus, this reference provides additional evidence that optimization of the ratio of the two [CLA] moieties was not within the routine skill of the artisan.

Moreover, Cain *et al.* is completely silent as to isomers of CLA other than 9,11 or 10,12. In fact, the publication defines CLA as containing up to eight different isomers, all of which are a 9,11 or 10,12 isomer (see page 1, lines 17-20). Thus, the reference is completely silent as to the presence or absence of other octadecadienoic acids, and so it is not possible to state that "no other isomer was employed for the esterification forming the acylglycerol composition" as the Examiner did (Office Action, page 2).

In fact, the Examiner appears to be completely ignoring an element of the claims, which is that the R groups of the acylglycerol comprise "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid." Since Cain *et al.* is completely silent about any other isomers of octadecadienoic acid, the reference does not even suggest, much less teach, this claim element. And the Examiner cannot pick and choose which elements are important, and which are not. In order to make a *prima facie* case of obviousness, all claim limitations must be taught or suggested (MPEP 2143.03). "All words in a claim must be considered in judging the patentability of that claim against the prior art." (MPEP 2143.03, citing *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)). Furthermore, the results in the Sugano *et al.* reference described above suggest that the fatty acid product produced by Cain *et al.* would have a lower degree of purity

than even that produced by Sugano, and that products produced as described in either reference are less pure than the fatty acid product claimed by the Applicants. Because the Examiner has not shown how this reference teaches or suggests all the claim elements, the Examiner has not met this requirement to make a *prima facie* case of obviousness, and on this ground alone the claims are not obvious.

Moreover, the Examiner has not indicated how Cain *et al.* can be modified to arrive at the Applicants' invention, absent the information provided in the Applicants' specification. Nor has the Examiner provided a motivation to do so; for example, why would one be motivated to provide a composition in which the R groups of acylglycerol comprise "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic and trans-trans octadecadienoic acid," if it was not recognized that the presence of these fatty acid moieties was a problem, or indeed if it was not recognized that these fatty acid moieties even existed? Therefore, the Examiner has failed to make a *prima facie* case of obviousness, and the Applicants respectfully request that the rejection of the claims over Cain *et al.* be withdrawn.

2. Claims 5-8 and 13-17 are rejected under 35 U.S.C. §103(a) as allegedly obvious over Nilsen *et al.* (U.S. Pat. No. 5,885,594) in view of Cook *et al.* (U.S. Pat. No. 5,554,646), further in view of Chin *et al.* (IDS April 13, 2000, 39). A rejection of Claims 5-8 was made in both the first and the final Office Action over the same first two references, and appears to have been maintained in this Office Action.

The Examiner asserts that Nilsen *et al.* teach a composition comprising 90-100% of an acylglycerol compound, where the fatty acid radical is a conjugated polyunsaturated fatty acid, preferably conjugated linoleic acid which is defined as c9,t11-octadecadienoic acid and/or c10,t12-octadecadienoic acid (Office Action, page 3). The Examiner admits that Nilsen *et al.* does not teach expressly the specific amounts of each of the two isomers, c9,t11-octadecadienoic acid and/or c10,t12-octadecadienoic acid, or the employment of the composition in animal feed. But the Examiner states that "Cook *et al.* teach that both c9,t11-octadecadienoic acid and/or c10,t12-octadecadienoic acid, and that their mixture is beneficial for animal health" (Office Action, page 3). The Examiner concludes that it would have been obvious to make the composition of Nilsen *et al.* with acylglycerol compounds wherein the

fatty acid moiety is a mixture of about equal parts c9,t11-octadecadienoic acid and/or c10,t12-octadecadienoic acid (Office Action, page 3). The Examiner further notes that Nilsen *et al.* do not use other isomers of conjugated linoleic acids, and that therefore the references meet the limitation set forth in claim 5 that other isomers are present in amounts less than 1% (Office Action, page 3). Finally, the Examiner states that Chin is cited to show that "a person of ordinary skill possesses the skill of preparing/or isolating the single pure isomer employed" in the invention (Office Action, page 4).

The Applicants first point out that the element to which the Examiner refers as "other isomers present in amounts less than 1%" is correctly "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub>."

The Applicants next point out that Chin *et al.* does not teach what the Examiner states that it does, and that it is irrelevant to the presently claimed invention. Chin *et al.* does not teach how to prepare or isolate single pure isomers; instead, page 697, left column, to which the Examiner refers simply shows a scan from a gas chromatographic separation of a sample of fatty acids. The conditions are not given, so it is not possible to know how to separate the fatty acids. Furthermore, samples analyzed by gas chromatography are generally very small, and not of suitable amounts for subsequent chemical reactions. Moreover, it is likely that the fatty acids are detected by flame ionization, which destroys the sample, and is thus the opposite of "preparing /or isolating" the fatty acids as stated by the Examiner. Thus, this reference is simply irrelevant to the presently claimed invention.

The Applicants next point out that the Examiner's discussion of the references above does not indicate how all of the claim elements are taught or suggested by the combination of the references. Thus, the Examiner does not assert that the combination teaches or suggests a composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, and at least approximately 30% c9,t11 octadecadienoic acid, at positions R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub>, as is presently claimed. The Examiner also asserts that the optimization of the ratio of the compounds is considered within ordinary skill; however, this assertion is not true for the reasons stated above.

The Examiner states that because Nilsen *et al.* do not use other isomers of conjugated linoleic acids, it meets the limitation set forth in claim 5 that other isomers are present in amounts less than 1% (Office Action, pages 3-4). This is simply incorrect. The Examiner admits that Nilsen *et al.* define conjugated linoleic acid as "c9,t11-octacecadienoic acid and/or c10,t12-octadecadienoic acid" (Office Action, page 3); how can this definition include other isomers? In fact, Nilsen *et al.* is completely silent about other isomers; therefore, it cannot be concluded that this reference meets a claim element which is essentially a measure of purity of a composition. The **absence** of a claim element in a reference cannot be interpreted to be the **presence** of this element. Because the Examiner has not shown how the combined references teach or suggest all the claim elements, the Examiner has not met this requirement to make a *prima facie* case of obviousness, and on this ground alone the claims are not obvious.

Moreover, the Examiner concludes that a motivation to combine the references is that c9,t11-octacecadienoic acid and/or c10,t12-octadecadienoic acid are known to be useful in food products. This is not a motivation to combine these two particular references to arrive at the claimed combination; at most, it is a conclusory statement that such a combination might be desirable. Nor has Examiner provided any reasonable expectation that even combining the two references would result in the Applicants' presently claimed invention. Therefore, the Examiner has failed to make a *prima facie* case of obviousness, and the Applicants respectfully request that the rejection of the claims over Nilsen *et al.* in view of Cook *et al.* and further in view of Chin *et al.* be withdrawn.

3. Claims 5-8 and 13-17 are rejected under 35 U.S.C. §103 as allegedly obvious over Timmermann *et al.* (WO 98/49129, No. 25 in the IDS of April 13, 200) in view of Cook *et al.* (U.S. Pat. No. 5,554,646), further in view of Chin *et al.* (IDS April 13, 2000, 39). A rejection of Claims 5-8 as allegedly obvious over the same first two references, made in the first Office Action, was implicitly withdrawn in the final Office Action, as it was not repeated in that Office Action. However, it appears to have been resurrected here.

The Examiner asserts that Timmermann *et al.* teach a composition for food comprising acylglycerol compounds where the fatty acid is conjugated linoleic acid, and admits that this

reference does not teach expressly the specific isomers [as in the presently claimed invention] (Office Action, page 4). The Examiner further asserts that Cook *et al.* "teach that both c9,t11-octadecadienoic acid and/or c10,t12-octadecadienoic acid, and that their mixture is beneficial for animal health" (Office Action, page 4). The Examiner then concludes that it would have been obvious to make the composition of Timmermann *et al.* with acylglycerol compounds wherein the fatty acid moiety is a mixture of about equal amounts of c9,t11-octadecadienoic acid and/or c10,t12-octadecadienoic acid, and employ the composition for animal feed. The Examiner also states that Chin is cited to show that "a person of ordinary skill possesses the skill of preparing/or isolating the single isomer employed" in the invention (Office Action, page 5).

The Applicants first point out that Chin does not teach what the Examiner states that it does, and that it is irrelevant to the presently claimed invention, for the reasons cited above. The Applicants next point out that the Examiner's discussion of the references does not indicate how all of the claim elements are taught or suggested by the combination of the references. Thus, the Examiner does not assert that the combination teaches or even suggests a composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, and at least approximately 30% c9,t11 octadecadienoic acid, at positions R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub>, as is presently claimed. The Examiner also asserts that the optimization of the ratio of the compounds is considered within ordinary skill, but this is not true for the reasons stated above. The Examiner also appears to be completely ignoring an element of the claims, which is that the R groups of the acylglycerol comprise "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic." The Examiner does not indicate how the combination of references would result in this claim element. Because the Examiner has not shown how the combination teaches or suggests all of the claim elements, the Examiner has not met this requirement to make a *prima facie* case of obviousness, and on this ground alone the claims are not obvious.

Moreover, the Examiner concludes that a motivation to combine the references is that c9,t11-octadecadienoic acid and/or c10,t12-octadecadienoic acid are known to be useful in food products. This is not a motivation to combine these two particular references; at most, it is a conclusory statement that such a combination might be desirable. Finally, the Examiner



has not provided any reasonable expectation that even combining the two references would result in the Applicants' presently claimed invention. Therefore, the Examiner has failed to make a *prima facie* case of obviousness, and the Applicants respectfully request that the rejection of the claims over Timmermann *et al.* in view of Cook *et al.*, and further in view of Chin *et al.* be withdrawn.

### **The Examiner's Comments on the Applicants' Previous Response Are Unclear**

The Applicants thank the Examiner for providing comments on their previous Response (filed April 9, 2001), which are to indicate why the Applicants' remarks were found to be unpersuasive. However, the Applicants do not understand the meaning of these comments.

With regard to the Applicants' argument that the "cited references do not teach each and every limitation of the claims" (Office Action, page 5), the Examiner noted that a question under "103 is not merely what reference expressly teach, but what they would suggest to one of ordinary skill," and that "all disclosures, including unpreferred embodiments, must considered" (citation omitted, Office Action page 5). The Examiner concluded that one of skill had both the motivation and method to making and using the claimed invention (Office Action, pages 5-6). The Applicants are uncertain as to what the Examiner means by these comments. The Applicants note that one requirement to establish a *prima facie* case of obviousness is that a reference or combination of references must teach or suggest all of the elements of the claims; the Applicants have pointed out that the references cited by the Examiner do not do this. Although the Examiner refers to "unpreferred embodiments," the Applicants point out that in the references cited, there are no unpreferred embodiments which would teach or suggest claim elements; instead, there is no disclosure at all regarding the missing claim elements, as discussed above. An "unpreferred embodiment" is not the same thing as no disclosure at all.

The Examiner further states that the Applicants asserts that "the claim does not read on composition made by any process because the traditional (industrial) method could not make the composition as claimed," and that a "composition claim would read on composition made by any method" (Office Action, page 6). The Applicants noted that the cited references did

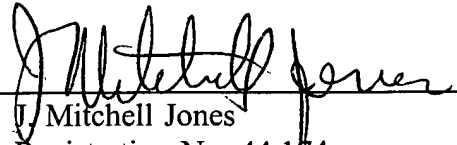
not disclose or even suggest the claimed composition; in response to the Examiner's conclusion that "optimization of ratios of the compounds" is routine, the Applicants provided additional evidence suggesting that even the cited combination of references would not result in the claimed composition, and that optimization of ratios was not routine. The Examiner also states that "it is the examiner's belief that isolation of a known organic compound is within the skill of artisan, absent evidence to the contrary" (Office Action). On its own, this is an extraordinary statement, as it is not uncommon that organic compounds can be known but not easily or routinely isolated. Furthermore, the Applicants have provided evidence to the contrary with respect to the presently claimed invention, as noted above. Finally, the Examiner asserts that the Applicants "assertion is not probative, because composition does not contains (and could not contain) any limitations with respect to quantity" (Office Action, page 6). To what composition is the Examiner referring? If it is a composition in the references, then this statement supports the Applicants position that the references do not teach or even suggest every element of the claims. If it is a composition in the claims, then the Applicants point out that the claimed composition does contain quantitative elements.

Finally, the Examiner concludes that the "motivation and suggestion [to combine the references] are found both in the cited references and in the knowledge generally available" (Office Action, page 6). The Applicants point out that a motivation or suggestion to combine references is not simply based on a conclusion that references can be combined, or that it might even be desirable to combine them; instead, a legally cognizable motivation or suggestion is that which expressly or implicitly indicates that the particular cited reference or references can be specifically modified or combined, and when so modified or combined, will result in the particular claimed invention against which they are cited. Such motivation or suggestion cannot be found in the Applicants' specification; thus, it is improper to assemble references, based upon the claims, and then to modify or combine them to reject claims as obvious. To do so is to use hindsight, which is impermissible. That is why the first requirement to establish a *prima facie* case of obviousness is that of a motivation or suggestion to modify or combine the references in the first place. The Applicants submit that the Examiner has failed to provide such a motivation or suggestion.

**CONCLUSION**

All grounds of rejection of the Office Action of June 8, 2001, have been addressed, and therefore reconsideration of the application is respectfully requested. It is respectfully submitted that the claims are in condition for allowance. Should the Examiner have any questions, or if a telephone conference would aid in the prosecution of the present application, the Applicants encourages the Examiner to call the **undersigned** collect at **608-218-6900**.

Dated: September 10, 2001

  
J. Mitchell Jones  
Registration No. 44,174

MEDLEN & CARROLL, LLP  
101 Howard St., Suite 350  
San Francisco, CA 94105  
415-904-6500

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**  
in accordance with 37 CFR 1.121(c)(1)(ii)

IN THE CLAIMS:

Claims 5 and 13 have been amended as follows:

5. (Amended three times) A biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub> attached at the positions of the OH- groups of a glycerol backbone, and wherein R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub> are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub>, wherein said percentages are peak area percentages as determined by gas chromatography.

13. (Amended three times) A composition comprising a prepared food product containing a biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub> attached at the positions of the OH- groups of a glycerol backbone, and wherein R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub> are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub>, wherein said percentages are peak area percentages as determined by gas chromatography.